REMARKS

Applicant wishes to thank the Examiner for the attention accorded to the instant application, and respectfully requests reconsideration of the application as amended.

The specification has been amended to remove all references to figures.

Claims 1, 5-13, 16-20, 24, 26-28, 30, 32-35 and 37-44 are pending in the application. Claims 14 and 36 have been canceled. Claim 1 has been amended. Support for this amendment can be found throughout the application generally, and page 9 lines 17-21, page 11 lines 1-9, page 15 lines 1-15 and Claim 14, specifically. No new matter has been added through this amendment.

Applicant respectfully submits new Claims 37-44 for examination. Claim 37 is directed to, *inter alia*, the subject being a mammal suffering from a disease or disorder selected from the group consisting of acidosis, osteoporosis and diarrhea. Claim 38 is directed to, *inter alia*, a method for preventing accumulation of lactic acid in the colon of a subject with a risk for imbalanced colon fermentation. Claim 39 is directed to, *inter alia*, a polydextrose being administered in combination with at least one polyol. Claim 40 is directed to, *inter alia*, the polydextrose being administered in a food composition selected from the group consisting of yogurt, baby's milk formula, sour milk, curdled milk, dry milk and crout. Claim 41 is directed to, *inter alia*, the polydextrose being administered in a food composition selected from the group consisting of yogurt, baby's milk formula, sour milk, curdled milk, dry milk and crout. Claim 42 is directed to, *inter alia*, the orally administrable food composition being selected from the group consisting of a dry, or semidry or liquid food product, a powder, a spray, a syrup, a sugar substitute, a candy or sweet, a dairy product, a frozen dairy product, a meat product, a health drink, a baby food, a pet food and an animal feed. Claim 43 is directed to, *inter alia*, the food

composition being a sour food or feed product. Claim 44 is directed to, *inter alia,* the food composition being selected from the group consisting of yogurt, baby's milk formula, sour milk, curdled milk, dry milk and crout.

No new matter has been added by way of the aforementioned Claim additions. For example, Applicant directs the Examiner's attention to page 9 lines 17-21, page 11 lines 1-9, page 15 lines 1-15 for support of new claims 37-41 and original claims 22, 23 and 25 for support of new claims 42-44. Applicant submits that the identified sections are presented only for the Examiner's convenience and is not intended to be an exhaustive list of support.

The specification is objected to for referring to figures which are not present.

Claims 1, 5-14, 16-20, 24, 26-28, 30 and 32-36 stand rejected under 35 U.S.C. §112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claims 1, 5-14, 16-20, 26-28, 30 and 32-36 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by Publication WO 00/40101 to Olinger et al. (hereinafter, "Olinger").

Claims 1, 5-13, 19, 27, 28, 35 and 36 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by Publication Am. J. Clin. Nutr. 2000, 72:1503-9 to Jie et al. (hereinafter, "Jie").

Claims 1, 5-14, 16-19, 27, 28, 30 and 32-36 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by U.S. Patent 5,711,982 (hereinafter, "Takemori").

Claims 1, 5-14, 16, 17, 19, 24, 26-28, 30 and 32-36 stand rejected under 35 U.S.C. §102(e) as allegedly anticipated by U.S. Patent Pub. 2003/0008843 (hereinafter, "Shaw Craig").

Claims 1, 5-13, 19, 27, 28, 35 and 36 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by Publication J. Lab. Clin. Med, May 1985, pages 585-592 to Solomons et al. (hereinafter, "Solomons").

Claims 20 and 24 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Jie.

Claim 26 stands rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Solomons in view of U.S. Patent 5,601,863 (hereinafter, "Borden").

Claims 1, 5-14, 16-20, 24, 26-28, 30 and 32-36 are provisionally rejected on the grounds of non-statutory obviousness-type double patenting over Claims 7-9, 11-15, 17-18, 22-26 and 28-30 of co-pending Application No. 10/341,748.

In view of the following remarks, Applicants request further examination and reconsideration of the present patent application.

Objections to the Specification

The specification is objected to for referring to figures which are not present. Reference to figures in Examples 2 and 3 have been removed. Withdrawal of this objection is earnestly solicited.

Rejections under 35 U.S.C. §112

Claims 1, 5-14, 16-20, 24, 26-28, 30 and 32-36 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Claim 1 has been amended to recite the treatment of a subject suffering from a disease or disorder caused by an accumulation of lactic acid in the colon. Based on the specification and the knowledge of one ordinarily skilled in the art, the meaning of Claim 1 is clear and the population to be treated is clear. The subject of Claim 1 is a subject who is suffering from a disease or disorder which is caused by an accumulation of lactic acid in the colon.

Therefore it is clear which population is to be treated and the rejection has been overcome. Withdrawal of the rejection of Claims 1, 5-14, 16-20, 24, 26-28, 30 and 32-36 under 35 U.S.C. §112, second paragraph and issuance of Claims 1, 5-14, 16-20, 24, 26-28, 30 and 32-36 is earnestly solicited.

Rejections under 35 U.S.C. §102

Claims 1, 5-14, 16-20, 26-28, 30 and 32-36 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by Olinger.

Claim 1 has been amended to recite a method to treat a subject suffering from imbalanced colon fermentation. Olinger does not disclose or teach a method to treat a subject suffering from imbalanced colon fermentation. Olinger discloses a dietetic chocolate composition comprising bulk sweetening agents, which provides an acceptable substitute for sucrose. See page 5 lines 2-14 of Olinger. The composition can be formulated to optimize caloric content, cariogenic properties, glycemie index, taste profile, texture and mouth feel, not colon fermentation. See page 7 lines 5-8 of Olinger. Where a patent claims a novel method of using a known product, that method is unanticipated, even when the benefit of the novel method may have been achieved accidentally by using the teachings of the prior art (emphasis added). This proposition is established in a US Federal Circuit decision, *Nicholas v. Perricone*, 432 F.3d 1368 (Fed. Cir. 2005).

Even if use of a combination of a polyol and an amount of polydextrose was known, Olinger does not disclose or suggest, the use of the combination of a polyol and an amount of polydextrose to reduce lactic acid accumulation in the colon by sustaining and controlling fermentation throughout the colon of said subject. Olinger is a deficient anticipatory reference

even though the steps of the method may be similar, the outcome of the steps provides a result that was not known, and not inherently anticipated.

For anticipation, "The mere fact that a certain thing may result from a given set of circumstances is not sufficient." As stated in a US Federal Circuit decision, *In re Robertson*, 169 F.3d 743 (Fed. Cir.1999). The mere fact that the composition disclosed in Olinger possibly could have been effective to reduce lactic acid accumulation in the colon by sustaining and controlling fermentation throughout the colon of a subject is not sufficient grounds to anticipate the present method claim.

Thus, Olinger is not an anticipatory reference, for at least the reason that the use of the combination of a polyol and an amount of polydextrose to reduce lactic acid accumulation in the colon by sustaining and controlling fermentation throughout the colon of said subject. Therefore, the rejection of Claims 1, 5-14, 16-20, 26-28, 30 and 32-36 under 35 U.S.C. §102(b) has been overcome. Withdrawal of the rejection and issuance of Claims 1, 5-14, 16-20, 26-28, 30 and 32-36 is earnestly solicited.

Claims 1, 5-13, 19, 27, 28, 35 and 36 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by Jie.

Jie discloses a drop in pH levels as polydextrose intake increases, which would aggravate a condition where a low pH level caused by lactic acid accumulation is causing an imbalance in colon fermentation. See p. 1507, Table 4 of Jie.

Claim 1 has been amended to recite a food product comprising a combination of at least one polyol and an amount of polydextrose. The subject matter of Claim 14 has been added to Claim 1. The Official Action correctly finds that Jie did not anticipate Claim 14, because Jie lacks a disclosure of a polyol.

Further, just because Jie states that there was no report of abdominal cramps and diarrhea, it does not follow that polydextrose can be used to counter diarrhea. See page 1505 right column of Jie. Moreover, just because a condition does not occur when a substance is taken, it does not mean that the substance prevented or cured the condition. Jie does not provide any evidence or proof that because the subjects received the polydextrose they did not have diarrhea, Jie simply states that no one reported it during their intake of polydextrose.

Further still, even if the steps of the method in Jie may be similar to the claimed invention, the outcome of the steps of the claimed invention provides a result that was not known, and not inherently anticipated.

Thus, Jie is not an anticipatory reference, for at least the reason that it does not disclose the use of at least one polyol, as claimed. Therefore, the rejection of Claims 1, 5-13, 19, 27, 28, 35 and 36 under 35 U.S.C. §102(b) has been overcome. Withdrawal of the rejection and issuance of Claims 1, 5-13, 19, 27, 28, 35 and 36 is earnestly solicited.

Claims 1, 5-14, 16-19, 27, 28, 30 and 32-36 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by Takemori.

Takemori discloses a low-calorie and sugar-less foodstuff which holds taste and feel of conventional foodstuffs thereby promoting health, not a method for therapeutically treating a subject suffering from imbalanced colon fermentation. See Column 2 lines 1-5 of Takemori.

Takemori does not disclose administering a food product comprising a combination of at least one polyol and an amount of polydextrose effective to reduce lactic acid accumulation in the colon because, as recited on page 8 of the Office Action, Takemori is silent as to accumulation of lactic acid in the colon.

For anticipation, "The mere fact that a certain thing may result from a given set of circumstances is not sufficient." See, *In re Robertson*, 169 F.3d 743 (Fed. Cir.1999). The mere fact that the composition disclosed in Takemori possibly could have been effective to reduce lactic acid accumulation in the colon by sustaining and controlling fermentation throughout the colon of a subject is not sufficient grounds to anticipate the present method claim. Further, Takemori does not provide any teaching that its method can be used to reduce lactic acid accumulation in the colon by sustaining and controlling fermentation throughout the colon of a subject.

Thus, Takemori is not an anticipatory reference, for at least the reason that it does not disclose administering a food product comprising a combination of at least one polyol and an amount of polydextrose. Therefore, the rejection of Claims 1, 5-14, 16-19, 27, 28, 30 and 32-36 under 35 U.S.C. §102(b) has been overcome. Withdrawal of the rejection and issuance of Claims 1, 5-14, 16-19, 27, 28, 30 and 32-36 is earnestly solicited.

Claims 1, 5-14, 16, 17, 19, 24, 26-28, 30 and 32-36 stand rejected under 35 U.S.C. §102(e) as allegedly anticipated by Shaw Craig.

Shaw Craig discloses the use of an agent to control an animal's appetite and food intake and to provide a feeling of fullness resulting from its ingestion. See Paragraph 24 of Shaw Craig. The method described in Shaw Craig does not disclose or provide any teaching to one of ordinary skill in the art that it would be useful or effective to treat a subject suffering from imbalanced colon fermentation.

For anticipation, "The mere fact that a certain thing may result from a given set of circumstances is not sufficient." See, *In re Robertson*, 169 F.3d 743 (Fed. Cir.1999). The mere fact that the composition disclosed in Shaw Craig possibly could have been effective to reduce

lactic acid accumulation in the colon by sustaining and controlling fermentation throughout the colon of a subject is not sufficient grounds to anticipate the present method claim.

Where a patent claims a novel method of using a known product, that method is unanticipated, even when the benefit of the novel method may have been achieved accidentally by using the teachings of the prior art (emphasis added). See, *Nicholas v. Perricone*, 432 F.3d 1368 (Fed. Cir. 2005). The present application claims a novel method of treating a subject suffering from imbalanced colon fermentation by administering a combination of at least one polyol and an amount of polydextrose effeetive to reduce lactic acid accumulation in the colon.

Thus, Shaw Craig is not anticipatory, for at least the reason that it does not disclose administering a food product comprising a combination of at least one polyol and an amount of polydextrose. Therefore, the rejection of Claims 1, 5-14, 16, 17, 19, 24, 26-28, 30 and 32-36 under 35 U.S.C. §102(e) has been overcome. Withdrawal of the rejection and issuance of Claims 1, 5-14, 16, 17, 19, 24, 26-28, 30 and 32-36 is earnestly solicited.

Claims 1, 5-13, 19, 27, 28, 35 and 36 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by Solomons.

Solomons discloses the use of polydextrose as a low-calorie bulking agent in weight-reducing diets, where the polydextrose is aimed at maintaining the familiar and appealing flavors and textures of foods while replacing part of the carbohydrate and fat. See Page 585 of Solomons. The Office Action correctly states that Solomons is silent on the accumulation of lactic acid in the colon. The method described in Solomons does not disclose or provide any teaching to one of ordinary skill in the art that it would be useful or effective to treat a subject suffering from imbalanced colon fermentation.

For anticipation, "The mere fact that a certain thing may result from a given set of circumstances is not sufficient." See, *In re Robertson*, 169 F.3d 743 (Fed. Cir.1999). The mere fact that the composition disclosed in Solomons possibly could have been effective to reduce lactic acid accumulation in the colon by sustaining and controlling fermentation throughout the colon of a subject is not sufficient grounds to anticipate the present method claim.

Where a patent claims a novel method of using a known product, that method is unanticipated, even when the benefit of the novel method may have been achieved accidentally by using the teachings of the prior art (emphasis added). See, *Nicholas v. Perricone*, 432 F.3d 1368 (Fed. Cir. 2005). The present application claims a novel method of treating a subject suffering from imbalanced colon fermentation by administering a combination of at least one polyol and an amount of polydextrose effective to reduce lactic acid accumulation in the colon.

Thus, Solomons is not an anticipatory reference, for at least the reason that it does not disclose administering a food product comprising a combination of at least one polyol and an amount of polydextrose. Therefore, the rejection of Claims 1, 5-13, 19, 27, 28, 35 and 36 under 35 U.S.C. §102(b) has been overcome. Withdrawal of the rejection and issuance of 1, 5-13, 19, 27, 28, 35 and 36 is earnestly solicited.

Rejections under 35 U.S.C. §103

Claims 20 and 24 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Jie.

The deficiencies of Jie are set forth above. Jie does not teach or suggest a method for therapeutically treating a subject suffering from imbalanced colon fermentation, the method comprising administering to the subject a food product comprising a combination of at least one polyol and an amount of polydextrose effective to reduce lactic acid accumulation in the colon,

which is a claimed element of both Claims 20 and 24. Therefore, Claims 20 and 24 are not obvious in view of the disclosure of Jie.

Thus, Jie does not render the claimed invention obvious for at least the reason that it does not teach or suggest a method for therapeutically treating a subject suffering from imbalanced colon fermentation by administering a food product comprising a combination of at least one polyol and an amount of polydextrose. Therefore, the rejection of Claims 20 and 24 under 35 U.S.C. §103(a) has been overcome. Withdrawal of the rejection and issuance of 20 and 24 is earnestly solicited.

Claim 26 stands rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Solomons in view of U.S. Patent 5,601,863 (hereinafter, "Borden"). The deficiencies of Solomons are set forth above; Borden does not cure these deficiencies. Borden discloses a polydextrose composition having improved color, flavor and decreased reactivity toward food ingredients. See Column 1 lines 51-58 of Borden. Borden does not teach or suggest a method for therapeutically treating a subject suffering from imbalanced colon fermentation, the method comprising administering to the subject a food product comprising a combination of at least one polyol and an amount of polydextrose effective to reduce lactic acid accumulation in the colon, as recited in Claim 26 of the present application.

The combination of Solomons and Borden would not render the claimed invention obvious to one of ordinary skill in the art because neither reference, provides a teaching or disclosure of using a combination of at least one polyol and polydextrose in a method for treating a subject suffering from imbalanced colon fermentation.

Thus, the combination of Solomons and Borden does not render the claimed invention obvious for at least the reason that it does not teach or suggest a method for therapeutically

treating a subject suffering from imbalanced colon fermentation by administering a food product comprising a combination of at least one polyol and an amount of polydextrose. Therefore, the rejection of Claim 26 under 35 U.S.C. §103(a) has been overcome. Withdrawal of the rejection and issuance of 26 is earnestly solicited.

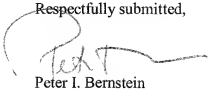
Rejections Under Double Patenting

Claims 1, 5-14, 16-20, 24, 26-28, 30 and 32-36 are provisionally rejected on the grounds of non-statutory obviousness-type double patenting over Claims 7-9, 11-15, 17-18, 22-26 and 28-30 of co-pending Application No. 10/341,748.

A terminal disclaimer for any patent term extending beyond the term of co-pending Application No. 10/341,748 was filed with the USPTO on 10/4/07 and was accepted by the USPTO on 10/19/07. Therefore this rejection is believed to be moot. Withdrawal of the rejection and issuance of Claims 1, 5-14, 16-20, 24, 26-28, 30 and 32-36 is requested.

Applicant believes that the paper submitted herein provides a complete response to the Office Action, and the present case is in condition for allowance. Therefore, in view of the foregoing, Applicant respectfully requests reconsideration, withdrawal of all rejections, and allowance of all pending claims in due course. If the Examiner believes that a telephone conference with the Applicants attorneys would be advantageous to the disposition of this case, the Examiner is requested to contact the undersigned, Applicant's attorney, at the number provided below.

Respectfully submitted,



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